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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,945	08/27/2003	Itzhak Bentwich	050992.0300.05USCP	1944

37808 7590 01/23/2009

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EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
01/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/604,945	BENTWICH, ITZHAK	
	Examiner	Art Unit	
	J. E. Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-23,33-35 and 45-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *21* is/are allowed.

6)☒ Claim(s) *22,23,33-35 and 45-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/13/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the communication filed on 11/13/2008.

The communication has been entered.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claims 21-23, 33-35, 45-47 are currently pending in the application and are addressed herein.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 11/13/2008 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 23, 35, 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection**.

37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

MPEP §2163.06 notes:

If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).

MPEP §2163.02 teaches that:

Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.

MPEP §2163.06 further notes:

When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure. (Emphasis added).

Claim 23 recites, "(a) a sequence at least 77.3% identical to SEQ ID NO: 5264". The recitation was added to claim 23 in the amendment filed 1/25/2008. Applicants have indicated that support can be found in Table 2 as well as paragraph 0014. However, Table 2, paragraph 0014, as well as the rest of the disclosure was reviewed, but sufficient support was not found. It is noted that claim 23, part (a) encompass a genus of nucleic acid molecules that includes all nucleic acid molecules at least 77.3% identical to SEQ ID NO: 5264. As such, the

claims encompass a large number of different nucleic acid molecules considering every possible nucleic acid molecule that is at least 77.3% identical to the 24mer sequence that is SEQ ID NO:5264; however, the specification appears to only identify one specific nucleic acid molecule of the claimed genus, that species being the nucleic acid molecule that is SEQ ID NO: 5294. It is acknowledged that the specification does describe that miRNAs can bind to target genes with less than 100% complementary (see paragraph 0014); however, the specification does not appear to provide a description sufficient to support the genus of molecules now encompassed by the claims. Therefore, it does not appear that, at the time of filing, applicants were in possession of the genus of molecules now claimed.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, the instant claims are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 34, 35, 46, 47 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/12234 (Jayasena et al.).

The instant claims are drawn to a vector and a probe comprising a nucleic acid sequence that is SEQ ID NO: 5264 or a nucleic acid sequence that is at least 77.3% identical to SEQ ID NO: 5264.

Jayasena teaches a nucleic acid sequence that comprises SEQ ID NO: 5264 as well as a vector comprising the sequence (see HIV –I TAR such as in Figure 1A of Jayasena, as well as the alignment below; page 43, etc.). It is noted that the term "probe" does not impart any structural requirement to the nucleic acid sequence in claims 46 and 47. Nevertheless, Figure 10 of Jayasena describes the oligonucleotides as an “oligo probe”. Therefore, Jayasena’s nucleic acid sequence SEQ ID NO: 26 anticipates claims 46 and 47.

Sequence Alignment:

```
AAQ44139

ID   AAQ44139 standard; RNA; 58 BP.

DT   13-DEC-1993  (first entry)

DE   Sequence of the TAR element of HIV-1.

PN   WO9312234-A1.
PD   24-JUN-1993.
PI   Jayasena SD,  Johnston BH;

  Query Match            100.0%;  Score 24;  DB 2;  Length 58;
  Best Local Similarity   100.0%;  Pred. No. 0.19;
  Matches   24;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 UCUCUGGUUAGACCAGAUCUGAGC 24
              ||||||||||||||||||||||||
Db          5 UCUCUGGUUAGACCAGAUCUGAGC 28
```

6. Claims 33, 45 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/50407 (Ludwig).

The instant claims are drawn to a vector and a probe comprising a nucleic acid sequence that is SEQ ID NO: 2194.

Ludwig teaches a nucleic acid sequence that comprises SEQ ID NO: 2194 as well as a vector comprising the sequence (e.g., see abstract; SEQ ID NO: 8; page 34 claim 5; etc., as well as the alignment below). It is noted that the term "probe" does not impart any structural requirement to the nucleic acid sequence in claim 45. Therefore, Ludwig's nucleic acid sequence anticipates the instant claims.

Sequence Alignment:

```
AAV81498

PN   WO9850407-A1.

PD   12-NOV-1998.

PI   Ludwig LB;
PT   antisense regulation of gene expression in eukaryotic cells, in vitro or
PT   by gene therapy.

PS   Claim 5; Page 34; 53pp; English.

CC   The invention relates to a novel mechanism endogenous to eukaryotic cells
CC   for modulating gene expression at the transcriptional and/or
CC   translational level. The genetic regulatory elements designated antisense
CC   initiator sequence (aINR) are part of a natural antisense RNA negative
CC   regulatory system and are present downstream of at least one copy of a
CC   DNA and are in cis-orientation with respect to a sequence to be regulated
CC   in the DNA. The invention provides recombinant vectors for replication in
CC   eukaryotic cells, containing at least one copy of isolated, purified
CC   nucleic acid comprising an aINR. The aINR is linked to a DNA that is to
CC   be transcribed to antisense RNA. Eukaryotic cells containing this vector
CC   are used for expressing the RNA. The vectors are used to regulate
CC   expression of target genes in eukaryotic, especially mammalian, cells,
CC   i.e. they initiate transcription of RNA of negative strand polarity that
CC   forms an inactive duplex with sense transcripts of the same gene. The
CC   method may be applied to cell cultures or for gene therapy. The present
CC   sequence represents a HIV-1 nucleic acid comprising an aINR The aINR is
CC   situated downstream from the usual HIV-1 promoter and transcription start
CC   site. The HIV-1 aINR is oriented to generate a transcript opposite in
CC   direction, and complementary to the TAR region of known HIV-1
CC   transcripts. (Updated on 17-OCT-2003 to standardise OS field)


Qy          1 GUACUGGGUCUCUCUGGUUAGACCAGAUCUGAGCCUGGGAGCUCUCUGGCUAACUAGGGA 60
              |:||:||||:|:|:|:||::|||||||||:|:|||||:|||||||:|:|:||||:|||:|||||
Db         71 GTACTGGGTCTCTCTGGTTAGACCAGATCTGAGCCTGGGAGCTCTCTGGCTAACTAGGGA 130

Qy         61 ACCCACUGC 69
              |||||||:||
Db        131 ACCCACTGC 139
```

7. Claims 22, 23, 46, 47 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Application 2001/0053519 (Fodor et al.).

8. The instant claims encompass oligonucleotides including the 24mer sequence that is SEQ ID NO: 5264 as well as nucleic acid sequences at least 77.3% identical to SEQ ID NO: 5264.

9. Fodor teaches methods of making every possible oligonucleotide in the range of 10-25 nucleotides in length, as well as compositions comprising the oligonculeotides (e.g., see abstract; paragraph 0033; paragraphs 0048-0051; paragraphs 0060-0061; paragraphs 0101-0103; claims 1-7, 14, 17-21; etc.). Therefore, Fodor anticipates the instant claims.

Allowable Subject Matter

10. Claim 21 is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. E. Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 8:00 a.m.-6:00 p.m. .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/
Primary Examiner, Art Unit 1635